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## NOTICE OF ALLOWANCE AND FEE(S) DUE

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7590

10/08/2010

LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731

EXAMINER					
BURKHART, MICHAEL D					
ART UNIT	PAPER NUMBER				
1633					

DATE MAILED: 10/08/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,890	04/28/2000	ULRICH H. KOSZINOWSKI	203676	6925

TITLE OF INVENTION: RECOMBINANT VECTOR CONTAINING INFECTIOUS, VIRAL GENOME SEQUENCES GREATER THAN 100 KB, METHOD FOR PRODUCING SAME AND USE FOR THE MUTAGENESIS OF THE VIRAL SEQUENCES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	01/10/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

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If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

### PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

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or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where m

appropriate. All further ndicated unless correcte naintenance fee notifica	ed below or directed oth	ng the Patent, advance on herwise in Block 1, by (a	rders and notification a) specifying a new co	of m orresp	aintenance fees woondence address;	ill be and/or	mailed to the current of (b) indicating a separ	correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)			Fee(s	s) Transmittal. Thi rs. Each additional	s certif I paper	icate cannot be used for	domestic mailings of the or any other accompanying at or formal drawing, must	
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CHICAGO, IL 6	50601-6731							(Depositor's name)
								(Signature)
								(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVEN	TOR		ATTO:	RNEY DOCKET NO.	CONFIRMATION NO.
09/463,890	04/28/2000		LRICH H. KOSZINO				203676	6925
		ECTOR CONTAINING EFOR THE MUTAGENI			-	ENCES	GREATER THAN	100 KB,
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSUE	E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0		\$0		\$1510	01/10/2011
EXAM	INER	ART UNIT	CLASS-SUBCLASS					
BURKHART,	MICHAEL D	1633	435-320100					
<ul> <li>Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</li> <li>□ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</li> <li>□ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.</li> </ul>			(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to					
PLEASE NOTE: Unl recordation as set fort	less an assignee is ident h in 37 CFR 3.11. Comp GNEE	oletion of this form is NO	data will appear on the Ta substitute for filing (B) RESIDENCE: (C	he pa g an a CITY	tent. If an assignessignment. and STATE OR C	OUNT	TRY)	ocument has been filed for
lease check the appropr	iate assignee category or	categories (will not be pr	rinted on the patent):		Individual 🖵 Co	rporati	on or other private gro	up entity  Government
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_ ~ ~ •	<b>tus</b> (from status indicated s SMALL ENTITY statu	r e e e e e e e e e e e e e e e e e e e	h Applicant is no	long	er claiming SMAI	I ENT	ΓΙΤΥ status. See 37 CF	P 1 27(a)(2)
* *					<del>-</del>			e assignee or other party in
Authorized Signature					Date			
Typed or printed name Registration No								
n application. Confiden ubmitting the completed his form and/or suggesti	tiality is governed by 35 dapplication form to the tons for reducing this but irginia 22313-1450. DC	U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the	1.14. This collection i depending upon the i e Chief Information O	s esti indivi ifficer	mated to take 12 n dual case. Any co c, U.S. Patent and	ninutes mment Traden	to complete, including s on the amount of tim nark Office, U.S. Depa	by the USPTO to process) g gathering, preparing, and ne you require to complete rtment of Commerce, P.O. or Patents, P.O. Box 1450,

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09/463,890	09/463,890 04/28/2000 ULRICH H. KOSZINOWSKI		203676	6925	
23460 75	90 10/08/2010		EXAM	INER	
LEYDIG VOIT &	& MAYER, LTD	BURKHART, MICHAEL D			
	AL PLAZA, SUITE 49	000	ART UNIT	PAPER NUMBER	
180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731			1633 DATE MAILED: 10/08/201	0	

## **Determination of Patent Term Extension under 35 U.S.C. 154 (b)**

(application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
Nation of Allowability	09/463,890	KOSZINOWSKI ET AL.	
Notice of Allowability	Examiner	Art Unit	
	Michael Burkhart	1633	
The MAILING DATE of this communication appeal All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RID the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this apport or other appropriate communication <b>GHTS.</b> This application is subject to and MPEP 1308.	olication. If not include will be mailed in due	ed course. <b>THIS</b>
1. ☑ This communication is responsive to <u>the amendment dated</u>	<u>d 6/21/2010</u> .		
2. <b>☑</b> The allowed claim(s) is/are <u>36,37 and 40-70</u> .			
<ul> <li>3. Acknowledgment is made of a claim for foreign priority unallocation and an important priority and an important</li></ul>	e been received.  The been received in Application No  Cuments have been received in this received in t	national stage applica	
<ul> <li>THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.</li> <li>4. ☐ A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give DECLARATION (PTO-152) which give DEC</li></ul>	es reason(s) why the oath or declaratest be submitted. Son's Patent Drawing Review (PTO-9	tion is deficient. 948) attached	OTICE OF
<ul> <li>(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date</li> <li>Identifying indicia such as the application number (see 37 CFR 1)</li> </ul>	.84(c)) should be written on the drawin	ngs in the front (not the	back) of
each sheet. Replacement sheet(s) should be labeled as such in the			
6. ☐ DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT			vote the
Attachment(s)  1. Notice of References Cited (PTO-892)  2. Notice of Draftperson's Patent Drawing Review (PTO-948)  3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date  4. Examiner's Comment Regarding Requirement for Deposit of Biological Material	<ul> <li>5. ☐ Notice of Informal Part of Interview Summary Paper No./Mail Date</li> <li>7. ☐ Examiner's Amendment</li> <li>8. ☒ Examiner's Stateme</li> <li>9. ☐ Other</li> </ul>	(PTO-413), e nent/Comment	wance
/Michael Burkhart/ Primary Examiner, Art Unit 1633			

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The 35 USC 103 rejection set forth in the previous Office Action relies upon Messerle et al (1996) and Kemble et al (1996) to arrive at the claimed vectors and methods. Messerle et al teach two BACs that when used together in the same cell provide the claimed features, and Kemble et al teach the entire 230-kbp CMV genome arranged on eight cosmids which are all linearized, transfected, and then concatamerize into a molecule that closely mimics, or may be a near identical replica of, the CMV genome within the eukaryotic cell (see e.g. Fig. 1a of Brune et al, 2000, of record). Thus, applicants assertions that the methods of Kemble et al do not produce a CMV genome are unconvincing. However, the withdrawal of the 35 USC 103 rejection is not reliant upon applicants arguments. The proposed combination of Messerle and Kemble et al appears to have been attempted by the disclosure of Messerle et al, but did not result in the claimed vector as set forth above. That is, Messerle et al teach an attempt to incorporate a circular or concatamerized (i.e. the same type of genome taught by Kemble et al ) CMV genome into a single BAC vector, but failed to do so. Furthermore, the evidence and reasoning set forth in the declarations by Drs. Koszinowski and Messerle regarding the difficulty in applying prior art methods of cloning large (e.g. > 100-kbp) DNA fragments are an apt summary of the state of the art at the time the instant application was filed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1633

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/ Primary Examiner, Art Unit 1633